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December 8, 2003

Annual Report for Regular Session 2004

This annual report is filed pursuant to Act 192, SLH 2002 which requires the Joint Formulary Advisory Committee ("Committee") to report to the legislature on its activities and recommendations with respect to the prescriptive authority formulary for advanced practice registered nurses ("APRN").

a) History

In accordance with Act 192, SLH 2002, the Department of Commerce and Consumer Affairs ("DCCA") was charged with the responsibility of establishing a Committee composed of:

- (1) Two persons licensed as advanced practice registered nurses and appointed by the board of nursing;
- (2) Two persons licensed in medicine by the board of medical examiners and appointed by the board of medical examiners;
- (3) Three persons licensed as pharmacists and appointed by the board of pharmacy;
- (4) One representative of the John A. Burns school of medicine appointed by the dean of the University of Hawaii school of medicine; and
- (5) One representative from a school of nursing with an APRN program.

The purpose of the Committee is to recommend the applicable formulary for APRNs recognized by the board of nursing. The board of medical examiners shall consider the recommendations of the Committee in adopting the formulary.

- b) The board of nursing, board of medical examiners, board of pharmacy, school of nursing and the school of medicine submit for then Acting Director Noe Noe Tom's approval of the following representatives to the Committee:

- (1) Board of Nursing:
 - (a) Valisa Saunders, MSN, Geriatric Nurse Practitioner
 - (b) Diane Knight, MSN, Pediatric Nurse Practitioner
- (2) Board of Medical Examiners:
 - (a) Chiyomi Fukino, M.D.
 - (b) John Rausch, M.D.
- (3) Board of Pharmacy:
 - (a) Elwin Goo, R.Ph.
 - (b) James McElhaney, R.Ph.
 - (c) Guy Omura, R. Ph.
- (4) School of Nursing:

Nancy Smith, Ph.D., APRN
- (5) School of Medicine:

Kelley Withy, M.D.

All representatives were currently licensed and had no history of disciplinary action at the time of their appointments. Ms. Tom noted that an alternate would have to be chosen for Dr. Fukino as she had just been appointed the Director of the Department of Health. The Board of Medical Examiners' Executive Officer, Constance Cabral-Makanani, was informed that another M.D. would need to be appointed by the Board of Medical Examiners. The alternate chosen was Dr. Glenn Pang, M.D. Dr. Smith was unable to participate in the Committee meetings and was replaced by Anne Leake, APRN, Ph.D.

c) December 26, 2002

Committee members were sent a packet of information with a copy of Act 192; Chapter 457, HRS; Chapter 16-89C, HAR; and Chapter 16-89, HAR; and an agenda for the first meeting.

d) January 8, 2003

The Committee discussed and came to an understanding of the intent of Act 192 and the purpose for the Committee. After reviewing the Exclusionary Formulary attached to Chapter 16-89C, relating to APRN prescriptive authority, the Committee decided that it would:

- (1) Amend the Formulary by deleting current language relating to off-label usage because its practical application has been particularly onerous and cumbersome in all healthcare settings.
- (2) Wait to see what amendments the Board of Nursing (“BON”) Practice Committee would propose to the rules relating APRN prescriptive authority which was moved from the DCCA to the Board of Nursing by Act 192. In particular, the Committee was interested in the proposed changes to the collegial agreement which has been controversial among APRNs and MDs.
- (3) Request the BON Practice Committee to share its proposed rule amendments to the Board of Medical Examiners (“BME”) via Ms. Cabral. Ms. Cabral would share the changes with the BME and provide feedback to the Committee.
- (4) Proceed once feedback was received from the BME.
- (5) Would not attempt to amend the formulary by including controlled substances this year.

e) February 12, 2003

Ms. Cabral apprised the Committee that the BME (Chair was not present at the meeting) in reviewing the proposed change to the Formulary by deleting current language and adding new language based on industry guidelines (to the extent that it relates to off-label usage) had no problems.

The BME had a discussion regarding the changes proposed by the BON Practice Committee because of the deletion of the definition of the word “institution” and the affiliation to an institution by the physicians and APRN. The BME was concerned that there would be no requirement in the collegial agreement for the physician to be affiliated with the same institution as the APRN.

The Committee adopted the changes to the Formulary. The report summarizing the Committee’s recommendation would be formally sent to the BME. The BME would then need to send its report to the BON as to the changes to the Formulary. The BME would be asked for an informal opinion if controlled substances were included in the formulary in light of the collegial agreement changes proposed by the BON Practice Committee.

- f) The language on off-label usage was later rejected by the BME when the Chair of the BME was notified of the proposed change. The BME required more information on what organization would be providing the guidelines and what criteria is used in approving the guidelines. This required the Committee to meet and address the issues.

g) July 16, 2003

The Committee met and decided on final language that will replace off-label usage wording. The Committee also decided to address controlled substances. Keith Kamita, State Narcotics Enforcement Division Administrator, was asked to attend the next meeting to discuss any concerns he had with APRNs prescribing controlled substances.

h) July 30, 2003

Keith Kamita stated that the only way he would entertain the idea of APRNs prescribing controlled substances would be if they are supervised by MDs. He had no problems with other prescription drugs and the collegial relationship that now exists. If the APRNs adopt rules similar to that of physician assistants, he would then amend Chapter 329, HRS, relating to controlled substances.

i) August 13, 2003

The Committee's final meeting produced the final recommendation to the BME based on its meeting with Keith Kamita and its research and comparison of the educational backgrounds of the M.D., APRN, and Physician Assistant.

A grid was developed to show differentiation among the three practitioners. The Committee's recommendation was submitted to the BME for consideration. To date, the BME was still deliberating over the recommendation and have not reported back to the Committee.

The Committee proposed amendments to Chapter 89, HAR, to the extent that it relates to APRN prescribing controlled substances based on language in §16-85-49(8), HAR, relating to Physician Assistants prescribing controlled substances. These proposed amendments if adopted would apply only to controlled substances and not to other prescription drugs. The proposed amendments were submitted to the BON for consideration. No action has yet been taken by the BON.